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10/728,248

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EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

06/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/728,248

Applicant(s)

DICARLO ET AL.

Examiner

Rene Towa

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office action is responsive to an amendment filed March 14, 2007. Claims 1-21 are pending. No new claim has been added. Claim 15 has been amended. No claim has been cancelled. Claims 22-33 are finally withdrawn from consideration as pertaining to a non-elected invention.

### *Election/Restrictions*

2. Applicant's election with traverse of claims 22-33 in the reply filed on March 14, 2007 is acknowledged. The traversal is on the ground(s) that claims 22-27 correspond to original claims 3-8 and claims 28-33 include limitations of original claims 9-14. This is not found persuasive because when considering a restriction, one needs only look at the independent claims, not each and every claim of the disclosure. Moreover, claims 22-27 do not correspond to claims 3-8; neither do claims 28-33 include limitations of original claims 9-14. The Examiner notes that original claims 1-21 and new claims 22-33 are in part because:

a. While original claim 1 requires an axially moveable stylet," newly submitted claim 22 only requires a stylet moveable between a first and second position;

It is worth noting that, in claim 22, movement of the stylet need not be axial; in fact, it could be transverse in a manner similar to that of pocket knives.

b. While claim 1 further requires an axial movement that causes rotational movement of the stylet, newly submitted claim 22 only requires a stylet that rotates when moved from the first position to the second position;

It is worth noting that rotation of the stylet may be caused by an electronic motor; in fact, the entire movement and rotation may be carried out by a controller and a set of actuators; wherein one actuator causes the stylet to move from the first position to the second; and the second actuator simultaneously causes rotation of the stylet.

c. Finally, as previously explained, newly submitted claim 22 comprises a stylet block, which is not included in originally submitted claim 1.

As such, originally submitted claim 1 is clearly distinct from newly submitted claim 22, in part, due to the fact that newly submitted claim 22 does not require the particulars of originally submitted claim 1 and is thereof distinct thereof. Consequently, claims 22-27 do not correspond to claims 3-8; neither are claims 28-33 equivalents of original claims 9-14. Furthermore, Applicant is advised that when two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Objections***

2. The objections are withdrawn due to amendments.

#### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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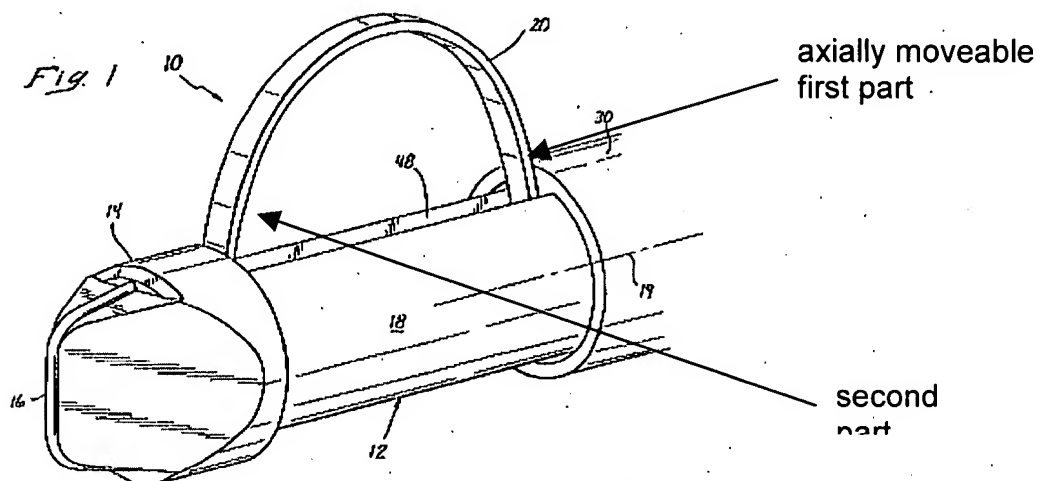
4. Claims 15-16 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. (US Patent No. 6,331,166).

In regards to claim 15, Burbank et al. discloses a method of using a medical instrument, the method comprising:

moving a stylet 18 and a stylet block 20 from a first position to a second position, the stylet block 20 having an axially moveable first part and a second part attached to the stylet 18, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet 18;

simultaneously causing rotation of the stylet 18 along an axis of the stylet 18 by engagement between second part of the stylet block 20 and a housing of the medical instrument; and

moving a cannula 30 over the stylet 18 (see fig. 1; column 4/lines 48-60; column 5/lines 38-42 & 44-49; column 7/lines 11-25 & 39-46).



In regards to claim 16, Burbank et al. discloses a method further comprising oscillating the stylet 18 along the axis (see column 7/lines 21-24).

In regards to claim 20, Burbank et al. discloses a method comprising rotating the stylet 18 in one direction (see column 7/lines 11-24).

In regards to claim 21, Burbank et al. discloses a method comprising rotating in multiple directions (see column 7/lines 11-24).

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US Patent No. 5,368,045) in view of Kornberg et al. (US Patent No. 5,197,484).

In regards to claim 1, Clement et al. discloses a medical instrument, comprising:  
a housing 8 having a proximal end 10 and a distal end 16;  
a stylet 18 having a portion in the housing, the stylet 18 being movable between a first extended position and a first retracted position; and  
a cannula 20 coaxially receiving the stylet 18 and having a portion in the housing 8, the cannula 20 being movable between a second extended position and a second retracted position (see figs. 1-2, 3a-d & 4a-4d; column 3/lines 4-16 & 22-32).

In regards to claim 2, Clement et al. discloses a medical instrument further comprising a stylet block 36 attached to a proximal end of the stylet 18 and mounted inside the housing 8 (see fig. 2).

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In regards to claim 3, Clement et al. discloses a medical instrument wherein the stylet block 36 comprises:

a first part inside the housing 8, the first part being moveable between an extended position and a retracted position (see fig. 2).

In regards to claim 9, Clement et al. discloses a medical instrument further comprising:

a stylet spring 44 capable of moving the stylet 18 from the first retracted position to the first extended position; and

a cannula spring 40 capable of moving the cannula 20 from the second retracted position to the second extended position (see fig. 2).

In regards to claim 10, Clement et al. discloses a medical instrument further comprising:

a first pivoting latch 52 capable of retaining the stylet 18 in a predetermined position when the stylet 18 is in the first retracted position; and

a second pivoting latch 60 capable of retaining the cannula 20 in a predetermined position when the cannula is in the second retracted position (see fig. 2).

In regards to claim 11, Clement et al. discloses a medical instrument wherein the stylet 18 comprises a notch 30 with a sharpened leading edge (see fig. 1c).

Clement et al. disclose an instrument, as described above, that teaches all the limitations of the claims except Clement et al. do not teach a stylet configured to rotate when moved from the first retracted position to the first extended position.

However, Kornberg et al. disclose an instrument including a part 91 attached to a proximal end of a stylet 54, the part 91 being rotatably engaged with a first part and being able to rotate relative to an axis of the stylet 54; wherein the housing 70 comprises a semi-cylindrical portion defining a track 158 configured to engage with the second part 91; wherein the second part 91 comprises: a projection 94 in contact with a track 158 associated with the housing 70, the projection 94 and track 158 capable of cooperating to axially rotate the second part 91 and the attached stylet 54 when the stylet 54 is moved between the first extended position and the first retracted position; wherein the track 158 is molded into the interior side of the housing 70; wherein the track 158 is configured to provide unidirectional rotation to the stylet 54; wherein the track is configured to provide multidirectional rotation to the stylet 54 (see figs. 9, 12, 17 & 28; column 2/lines 1-9; column 3/lines 39-50 & 52-66; column 4/lines 29-31, 39-42 & 49-61; column 8/lines 18-23 & 25-32; column 9/lines 25-40 & 53-61; column 10/lines 3-6 & 19-24; column 11/lines 27-34 & 46-53; column 12/lines 2-5, 25-32 & 40-47; column 13/lines 19-25; column 14/lines 26-34 & 45-47).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Clement et al. with a rotating stylet system similar to that of Kornberg et al. in order to automatically rotate the stylet as it penetrates tissue so as to facilitate tissue penetration as is well known in the art.



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7. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Kass (US Patent No. 5,921,943).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach two openings and an opening opposing the notch. However, Kass discloses an instrument comprising a stylet including two openings for a notch, which can also be viewed as a notch and an opening opposing the notch (which can be seen in Figure 19) for receiving tissue that has been cut by cutting cannula (see Column 9, lines 15-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga with a notch having two openings and an opening opposing the notch, as taught by Kass, for receiving tissue that has been cut by cutting cannula.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Haaga (US Patent No. 5,394,887).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach a notch comprising a ramped surface.

However, Haaga teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the

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tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clement et al. as modified by Kornberg et al. with a stylet having a notch with a ramped surface, as taught by Haaga to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

9. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. ('166) in view of Ritchart et al. (US Patent No. 5,649,547).

Burbank et al. disclose a method, as described above, that teaches all the limitations of the claims except Burbank et al. do not teach the step of collecting a sample in a notch of the stylet. However, Ritchart et al. disclose a method comprising the step of collecting a sample in a notch 28 of a stylet; wherein the method further comprises removing the sample from the notch 28 by inserting an object 22 through an opening located in the notch 28 (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Burbank et al. with a method step comprising removing the tissue through a notch similar to that of Ritchart et al. in order to conveniently collect the severed tissues (see Burbank et al., column 8/lines 39-46).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Burbank et al. as modified by Ritchart et al. with a step of removing the sample over an inclined surface since such a modification would amount to a design choice that would serve the same purpose of removing the severed tissue. Even moreover yet, the Applicant has not disclosed that removing the tissue over an inclined surface provides an advantage, is used for a particular purpose, or solves a stated problem.

### ***Response to Arguments***

10. Applicant's arguments filed March 14, 2007 have been fully considered but they are not persuasive. Applicant argues that Burbank does not teach rotation of a stylet that is caused by engagement to the housing. Applicant further argues that Kornberg does not teach a stylet that rotates when the device is rotated. These arguments have been considered but have not been deemed persuasive.

In regards to the Applicant's argument that Burbank does not teach a rotation of a stylet that is caused by engagement to the housing, the Examiner respectfully traverses. The Examiner notes that the second part of the stylet block 20, as described in the rejections supra, is engaged to the stylet 18, which stylet 18 is engaged to the housing 28 and/or rest of the device; and rotation of the stylet 18 is due to its attachment to the housing 28 and/or rest of the device; and rotation of the second part of the stylet block 20 is due, in part, to the attachment of the second part of the stylet block 20 to the stylet 18 and thus to the housing 28 and/or rest of the device (see column 5/lines 48-62); as such, rotation of the stylet 18 is fully due to its engagement to

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the housing 28 and/or rest of the device between the second part of the stylet block 20 and the housing or rest of the device. Moreover, a housing, when given a broad reasonable interpretation, may be construed as any portion of the device that supports or holds other elements rather than the narrow element 28 of Burbank, thus stylet 18 may well be considered the housing or a portion thereof. As such, the Examiner submits that Burbank teaches causing rotation of the stylet 18 by engagement between a part of a stylet block and a housing of the medical instrument.

In regards to the Applicant's argument that Kornberg does not teach a stylet that rotates when the device is rotated, the Examiner respectfully disagrees. The Examiner notes that the limitation "stylet," when given a broad reasonable interpretation, may well refer to a "slender surgical probe" (see *Webster's II New Riverside University Dictionary* (1994)). As such, Kornberg fully discloses a stylet 54, as described in the rejections above and as admitted by Applicant at page 9 of the Remarks dated March 14, 2007, that rotates when the device is actuated. Even if, arguendo, element 54 was only considered a cannula, the Applicant is reminded that of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It clearly remains obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that Clement et al. with a rotating stylet and/or cannula similar to that of Kornberg et al. in order to automatically rotate the stylet and/or cannula as it penetrates tissue so as to facilitate tissue penetration. As such, whether Kornberg explicitly discloses a stylet or a cannula is completely immaterial, since the motivation remains the same (i.e. to facilitate tissue penetration by means of a slender surgical probe, the slender probe may thus be a stylet, a cannula, a needle-like device, a surgical pin, etc.).

In view of the foregoing, the rejections are maintained.

#### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/

  
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